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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/376,317	08/18/1999	KENNETH B. STOKES	P-3569CON	6342

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EXAMINER
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WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 08/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/376,317

Applicant(s)

STOKES ET AL.

Examiner

Anne Marie S. Wehbe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/3/04</u> . | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

Applicant's petition under 37 CFR 1.137(b) submitted on 12/10/04 to revive the instant application, previously abandoned- see Notice of Abandonment mailed to applicants on 1/19/03 - was granted on 1/18/05. The request for continued examination, amendment, and response submitted along with the petition on 12/10/04 have been entered. In response to the amendment, a Notice of non-compliant amendment letter was mailed to the applicants on 2/2/05. Applicant's amendment in response to this letter was received on 3/4/05 and has also been entered.

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/10/04 has been entered. Applicant's response filed on 12/10/04 has also been entered, along with the amendment filed on 2/2/05.

***Status of the Claims***

Applicant's amendment filed on 2/2/05 does not comply with 37 CFR 1.121. First, the amendment does not list the status of all claims filed in the application. Claim 61 was added by amendment on 11/6/00, and then canceled in the amendment received on 9/4/01. The amendment does not list claim 61. Second, the amendment lists claims 2-3, 15-19, 26-38, 43-47, and 51-60

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as withdrawn. Applicant's comments regarding the amendment filed on 2/2/05 also state that the instant application contains withdrawn claims. However, the file history of the instant application clearly shows that the applicant had previously canceled all of claims 2-3, 15-19, 26-38, 43-47, and 51-60. The case history shows the following: claims 2-3 and 26-38 were canceled by the amendment filed on 8/18/99; claims 55-60 were canceled by the amendment filed on 11/6/00; claims 15-19, 43-47, and 51-61 were canceled by amendment on 9/4/01, thus reiterating the cancellation of claims 55-60 (note also that the 1/17/02 and 4/29/02 amendments reiterates these cancellations); and finally claims 1, 4-14, 21-25, 39-42, and 48-50 were canceled by the amendment filed on 12/10/04. Thus, claims 1-19, and 21-61 are all canceled in the instant application. **As a result of these cancellations, only claim 20 is pending in this application.**

Since the deficiencies of this amendment do not preclude examination, the examination of claim 20 proceeds. However, all future amendments submitted to the office must comply with the requirements of 37 CFR 1.121 and must correctly identify the status of all the claims. Thus, any future amendments must list claims 1-19, and 21-61 as canceled.

Claim 20 is the only claim pending in this application. Claim 20 is currently under examination. An action on the merits follows.

The text of those sections of Title 35 , US code, not included in this office action may be found in previous office actions.

***Claim Rejections - 35 USC § 112***

The rejection of claims 1, 4-14, 20-25, 39-42, and 48-50 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn over canceled claims 1, 4-14, 21-25, 39-42, and 48-50, and withdrawn over claim 20 in view of applicant's amendments to the claims and arguments. Specifically, the applicant has amended the claims to recite that the delivery means results in the transfection or transduction of the vectors into cardiac tissue, that the mapping electrode means provides the means of determining the location of cardiac tissue deficient in connexin expression for transfection or transduction, and that the pacing electrode means provides means for testing or controlling the effect of the expressed connexin proteins with a pacemaker. In view of these amendments and applicant's arguments that 1) neither the pacing or mapping electrode means are equivalent to electroporation electrodes and are not meant to deliver the vectors through electroporation, and 2) similar patents have been obtained by the applicants for implantable delivery systems for delivering doses of genetic material capable of expressing other conduction proteins such as ion channel proteins, the rejection of record has been withdrawn.

Applicant's amendments to the claims have necessitated the following new grounds of rejection under 35 U.S.C. 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 20 is newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim as amended is confusing such that metes and bounds of the claim cannot be determined.

First, the claim now recites a delivery means for delivering and transfecting or transducing a therapeutically effective amount of the recombinant nucleic acid vectors from said reservoir means through said distal tip portion of said catheter to cardiac tissue. However, it is unclear from the claim as written where the reservoir means containing the vectors is located in relation to the delivery means and the catheter such that the vectors can in fact be delivered to the cardiac tissue through the distal tip portion of the catheter.

Second, based on the amended claim language, it is unclear whether the applicant intends the delivery means to both deliver the vector **and** actively transfect or transduce the cardiac tissue with the vector. If the applicant intends the delivery device to function solely to deliver the vector, it is suggested that the claim be amended to recite, “a delivery means for delivering a therapeutically effective amount of said recombinant nucleic acid vectors from said reservoir means through said distal tip portion of said catheter to said cardiac tissue **such that said cardiac tissue to transfect or transduced with said recombinant nucleic acid vectors**”.

Third, the claim lacks antecedent basis for “said connexin proteins”. The claim refers to a conduction protein selected from the group Cx40, Cx43, and Cx45. Further, the claim as written lacks a step wherein the encoded protein are actually expressed in the cardiac tissue following transfection/transduction.

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Finally, the claim appears to contain a typographical error. The claim misspells “transducing” as “transducting”.

***Claim Rejections - 35 USC § 103***

The rejection of claims 1, 4-9, 12-14, 24-25, 39-42 under 35 U.S.C. 103(a) over Mulier et al. in view of Leiden et al. and Kanter et al. is withdrawn in view of applicant’s cancellation of claims 1, 4-9, 12-14, 24-25, and 39-42.

It is noted that the applicant lists claim 20 as having been included in this rejection. However, claim 20 does not stand rejected under 35 U.S.C. 103. Please see the office actions mailed on 2/2/01, 12/19/01, and 6/20/02. In particular, the non final office action mailed on 2/2/01 sets forth on page 10 that the 103 rejection was in fact withdrawn over claim 20 in the non-final rejection. Therefore, applicant’s arguments regarding the obviousness of claim 20 are moot.

Claim 20 is considered free of the prior art of record. Although the art teaches catheter based systems for delivery nucleic acid vectors to the heart, the prior art of record does not teach or suggest a delivery system for cardiac tissue comprising the combination of a pacing electrode, a mapping electrode, a catheter, and a reservoir containing nucleic acid vectors encoding Cx40, Cx43, or Cx45.

Please note as well, that although the applicant states in their response that two patents belonging to applicants have been issued to “essentially the same systems for delivery”, neither

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statutory nor obviousness type double patenting applies as none of applicant's issued patents, 6,567,705, 6,665,563, or 6,801,805, claim or disclose a delivery system which comprises both a pacing electrode and a mapping electrode. None of the aforementioned patents discloses mapping electrodes, or in particular, mapping electrodes that determine the location of cardiac tissue deficient in connexin expression.

No claims is allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER

